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## NOTICE OF ALLOWANCE AND FEE(S) DUE

7590

02/26/2002

Dennis M Connolly  
Nixon Peabody  
Clinton Square  
PO Box 1051  
Rochester, NY 14603

EXAMINER

CHAKRABARTI, ARUN K

ART UNIT

CLASS-SUBCLASS

1634

435-091100

DATE MAILED: 02/26/2002

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,061	09/01/2000	Tsugunori Notomi	201487/1020	7501

TITLE OF INVENTION: PROCESS FOR SYNTHESIZING NUCLEIC ACID

TOTAL CLAIMS	APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
19	nonprovisional	NO	\$1280	\$0	\$1280	05/28/2002

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN **THREE MONTHS** FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

## HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above. If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

B. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

- ☐ Applicant claims SMALL ENTITY status.  
See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

# **PART B - FEE(S) TRANSMITTAL**

**Complete and mail this form, together with applicable fee(s), to:**

**Box ISSUE FEE  
Assistant Commissioner for Patents  
Washington, D.C. 20231**

**MAILING INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

7590 02/26/2002

Dennis M Connolly  
Nixon Peabody  
Clinton Square  
PO Box 1051  
Rochester, NY 14603

Note: The certificate of mailing below can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

## **Certificate of Mailing**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,061	09/01/2000	Tsugunori Notomi	201487/1020	7501

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19	nonprovisional	NO	\$1280	\$0	\$1280	05/28/2002

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHAKRABARTI, ARUN K	1634	435-091100

<p>1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Use of PTO form(s) and Customer Number are recommended, but not required.</p> <p><input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.</p> <p><input type="checkbox"/> "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47) attached.</p>	<p>2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.</p> <p>1. _____</p> <p>2. _____</p> <p>3. _____</p>
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## **3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)**

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) ☐ individual ☐ corporation or other private group entity ☐ government

## **4a. The following fee(s) are enclosed:**

- ☐ Issue Fee
- ☐ Publication Fee
- ☐ Advance Order - # of Copies \_\_\_\_\_

## **4b. Payment of Fee(s):**

- ☐ A check in the amount of the fee(s) is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

<p>(Authorized Signature)</p>  <p>NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.</p> <p>Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending on the needs of the individual case. Any comments on the amount of time required to complete this form should be sent to the Chief Information Officer, United States Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND FEES AND THIS FORM TO: Box Issue Fee, Assistant Commissioner for Patents, Washington, D.C. 20231</p> <p>Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.</p>	<p>(Date)</p>
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TRANSMIT THIS FORM WITH FEE(S)



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,061	09/01/2000	Tsugunori Notomi	201487/1020	7501
7590 Dennis M Connolly Nixon Peabody Clinton Square PO Box 1051 Rochester, NY 14603			EXAMINER CHAKRABARTI, ARUN K	
			ART UNIT 1634	PAPER NUMBER 18
DATE MAILED: 02/26/2002				

**Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**  
(application filed on or after May 29, 2000)

The patent term adjustment to date is 0 days. If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the term adjustment will be 0 days.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (<http://pair.uspto.gov>)

# Notice of Allowability

Application No.  
09/530,061

Applicant(s)  
Notomi et al.

Examiner  
Arun Chakrabarti

Art Unit  
1655



--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/31/02 and 1/11/02
2. ☒ The allowed claim(s) is/are 29 and 42-59
3. ☒ The drawings filed on Sep 1, 2000 are acceptable as formal drawings.
4. ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/530,061
3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \*Certified copies not received:

5. ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

6. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
7. ☐ Applicant MUST submit NEW FORMAL DRAWINGS
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_
- (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the examiner.
- (c) ☐ including changes required by the attached Examiner's Amendment/Comment or in the Office action of Paper No. \_\_\_\_\_

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

8. ☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any reply to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

## Attachment(s)

- 1 ☐ Notice of References Cited (PTO-892)
- 2 ☐ Notice of Informal Patent Application (PTO-152)
- 3 ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 4 ☒ Interview Summary (PTO-413), Paper No. 18
- 5 ☒ Information Disclosure Statement(s) (PTO-1449), Paper No(s). 11
- 6 ☐ Examiner's Amendment/Comment
- 7 ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 8 ☒ Examiner's Statement of Reasons for Allowance
- 9 ☐ Other

Art Unit:

## DETAILED ACTION

### *Reasons for Allowance*

1. The following is an examiner's statement of reasons for allowance: The present invention is directed to a method of amplifying a nucleic acid comprising:

a) providing a template having (I) a 3' end portion comprising a first region located 3' terminal and a first complementary region which, under suitable conditions, anneal to one another to form a first loop, (ii) a 5' end portion comprising a second region located 5' terminal and a second complementary region which, under suitable conditions, anneal to one another to form a second loop, and (iii) a region connecting the 3' end portion and the 5' end portion;

b) extending the 3' terminal of the template to the 5' end of the template;

c) annealing to the first loop of the extended template an oligonucleotide primer comprising at the 3' terminal a nucleotide sequence complementary to at least part of the first loop and at the 5' terminal a nucleotide sequence complementary to the first region of the template;

d) extending the oligonucleotide primer;

e) further extending the 3' terminal of the extended template to the 5' end, when the third region and the third complementary region are annealed to one another to form the third loop, thereby displacing the new template from the extended template; and

f) repeating steps a)-e) using the new template as the template in step a), thereby amplifying the nucleic acid.

Art Unit:

Although, Cleuziat et al. (U.S. Patent 5,874,260) (February 23, 1999) disclose a method of amplifying a nucleic acid comprising:

a) providing a template having (I) a 3' end portion comprising a first region located 3' terminal and a first complementary region which, under suitable conditions, anneal to one another to form a first loop, (ii) a 5' end portion comprising a second region located 5' terminal and a second complementary region which, under suitable conditions, anneal to one another to form a second loop, and (iii) a region connecting the 3' end portion and the 5' end portion;

b) extending the 3' terminal of the template to the 5' end of the template;

c) annealing to the first loop of the extended template an oligonucleotide primer comprising at the 3' terminal a nucleotide sequence complementary to at least part of the first loop and at the 5' terminal a nucleotide sequence complementary to the first region of the template,

Cleuziat et al. do not teach further extending the 3' terminal of the extended template to the 5' end, when the third region and the third complementary region are annealed to one another to form the third loop, thereby displacing the new template from the extended template; and

f) repeating steps a)-e) using the new template as the template in step a), thereby amplifying the nucleic acid.

In view of the absence of either teaching or suggestion of such an amplification method further extending the 3' terminal of the extended template to the 5' end, when the third region and

Art Unit:

the third complementary region are annealed to one another to form the third loop, thereby displacing the new template from the extended template; and

f) repeating steps a)-e) using the new template as the template in step a), thereby amplifying the nucleic acid, the present invention is novel and non-obvious.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### *Conclusion*

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Application/Control Number: 09/530,061

Page 5


Art Unit:

Arun Chakrabarti

Patent Examiner

Art Unit 1655

February 8, 2002



W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600